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DRY LIVE AEROSOL ANTHRAX VACCINE

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DRY LIVE AEROSOL ANTHRAX VACCINE

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As a result of the many years of study on the development of an aerosol method of immunization against anthrax, dry live aerosol vaccine was obtained which was studied extensively in the far-ranging experiments on animals and a limited number of people.

The results derived from the development of the aerosol method of immunication with the anthrax vaccine confirm the need for a further study concerning the safety, reactogenicity, and effectiveness of this immunication method, and also the need to improve the methods for obtaining the aerosol vaccine with high biological activity and good aerodispense properties for immunization of large contingents.

In this work we present the results of the studies carried out in 1965 on the improvement of dry live aerosol anthrax vaccine.

To produce this preparation, a spore culture of one anthrax vaccine strain, STI-1, was used instead of the mixture of two

strains (STI-1 and No. 3), which simplified the technological process considerably.

Anthrax vaccine strain STI-1 was cultured in the Shesterenko apparatus used for growing microbes (AKMSh), which provided us with large amounts of spore culture.

A 24-hour culture of the STI-1 anthrax vaccine strain grown in a separating flask at 34° was used as the seeding material. A 24-hour culture of the STI-1 strain washed with a physiological solution from 1-2 separating flasks was diluted 5 l of physiological solution and, after obtaining the pure culture, growth characteristic, pH value, and concentration of the microbes (according to the optical standard), was planted on agar medium in the AKMSh.

Immediately after the mother culture was planted, automatic aeration system was turned on and the apparatus was placed at a certain angle to the vertical axis - at 7° for the first two days and at 60° for the remaining culture time.

Air was supplied to the apparatus through out the entire culture period (5 days) at the rate of 25 l per minute, for 20 min every 2 h. Under such conditions of aeration the spore-culture yield, both when checked by the optical standard and by the amount of spores in 1 ml of wash, was higher as compared with the aeration for only 48 h. The incubation temperature was maintained between 34 and 35°.

Using this culture technique we were able to obtain large amounts of spore culture (6-6.5 l from a single load of the apparatus) with a concentration of 3-10 billion spores per 1 ml, of which 70-80% were viable.

The STI-1 anthrax vaccine strain, both in the flasks and in AKMSh, was cultured on the agar media based on tryptic hydrolysate

of meat or fresh fish.

To increase the concentration of spores in 1 g of dry vaccine, distilled water was used to wash out the spore culture from the AKMSh and also as the drying medium, instead of the stabilizer (a mixture of sugars with peptone) used earlier. In this case the spore content in 1 g of dry vaccine increased by 2-3 times (50-87 billion/g) as compared to the vaccine prepared with the stabilizer (20-30 billion/g), and the number of viable spores in the prepared vaccine did not diminish.

To ensure the necessary aerodisperse properties of the aerosol vaccine the composition of the latter includes an inert polydisperse substance (filler). The spore culture washed with distilled water from the agar medium in AKMSh was impregnated into the filler in the amounts of 100-150 billion spores for 1 g of filler, after which the spore culture with the filler was frozen at -45° and then dried in flasks in the KS-6 drier for 24-26 h. The drying was accomplished under vacuum (at the beginning of the drying period - 250-400 μ and toward the end at 100-180 μ Hg); the cassettes were heated to 40° for the first 8-10 h and to 30° until the end of the drying period.

The entire cycle in the preparation of the dry live aerosol vaccine lasted 7 days (1 day for the preparation of the seeding material, 5 days for culturing in the AKMSh, and 1 day for freezing and drying of the vaccine).

The use of the PAV-65 model during the aerosol vaccination, which ensures dispersion of the dry live aerosol anthrax vaccine during the spraying, has eliminated the step of preliminary pulverization of the preparation in the mill, which enabled us to obtain the vaccine free of other microflora.

The dispersion of the vaccine during spraying has enabled us to create a highly dispersed vaccine aerosol, as a result of which we were able to increase the use factor of the vaccine and decrease the amount of its weighted quantity for 1 m^3 of the building.

For a comparative evaluation of the suitability of the various series of the preparation for the aerosol immunization, the following "spraying criterion" was established experimentally: the magnitudes of the calculated aspiration dose of the preparation (aerosol concentration in 150 ℓ of air when spraying a weighted quantity of the vaccine at 0.05 g for 1 m^3 by the PAV-65 device) should be at least 1 mg. Under these conditions, a 15-min period of aerosol immunization provides the conditions for an individual to inhale (the lung capacity is equal to 10 ℓ on the average) at least one immunization dose (50 billion) of anthrax spores.

The study of all the series of dry live aerosol anthrax vaccine, prepared according to the technique described above has shown that the calculated aspiration dose of the preparations in which distilled water was used as the drying medium was more than 1 mg, i.e., these preparations based on the "spraying criterion," were suitable for aerosol use.

The storage conditions of the preparation (depth of vacuum and temperature) are an important factor in the preservation of the viability of spores in dry live aerosol anthrax vaccine....

In the absence of vacuum in the vials or flasks containing vaccine the content of live spores in the preparation decreased after 6 months of storage in a room refrigerator. A noticeable decrease in the content of live anthrax spores was observed also in vials and flasks with vacuum, in those instances when the vaccine was stored at 20°.

Conclusions

1. In preparing the dry live aerosol anthrax vaccine the use of a spore culture of the STI-1 single vaccine strain and culturing of the latter on a solid medium in the AKMSh has considerably simplified the culturing process and ensured large amounts of spore culture obtained with a concentration of up to 10 billion spores in 1 mm of wash.

2. Dry live aerosol anthrax vaccine is suitable for aerosol immunization if the calculated aspiration dose, when spraying the weighted quantity of the vaccine at 0.05 g for 1 m^3 of the building by the PAV-65 device, is at least 1 mg. Such conditions ensure that an individual will inhale at least one immunization dose of anthrax spores during a 15-min period of aerosol immunization.

3. For a prolonged storage of the viable spores in dry live aerosol anthrax vaccine, it is necessary to store it under deep vacuum (in the range of 100-150 μ) and at temperatures not exceeding +10°.